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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 09/508,661      | 05/26/2000  | JEAN-PIERRE SACHETTO |                     | 6789             |

2292 7590 11/02/2005

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EXAMINER

GEORGE, KONATA M

ART UNIT PAPER NUMBER

1616

DATE MAILED: 11/02/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

|                              |                  |                 |  |
|------------------------------|------------------|-----------------|--|
| <b>Office Action Summary</b> | Application No.  | Applicant(s)    |  |
|                              | 09/508,661       | SACHETTO ET AL. |  |
|                              | Examiner         | Art Unit        |  |
|                              | Konata M. George | 1616            |  |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

#### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

#### Status

- 1) ☒ Responsive to communication(s) filed on 16 August 2005.
- 2a) ☒ This action is **FINAL**.                      2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

#### Disposition of Claims

- 4) ☒ Claim(s) 1-3, 6, 15, 22, 24-27, 33, 37-39, 42, 43 and 45-56 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1, 2, 15, 27, 33 and 37-39 is/are rejected.
- 7) ☒ Claim(s) 3, 6, 22, 24-26, 42, 43 and 45-56 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

#### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

#### Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All    b) ☐ Some \*    c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

#### Attachment(s)

- |  |   |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)   | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)                                   | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____  |

### **DETAILED ACTION**

Claims 1-3, 6, 15, 22, 24-27, 33, 37-39, 42, 43 and 45-56 are pending in this application.

### ***Action Summary***

1. The rejection of claims 1 and 2 under 35 U.S.C. 102(b) as being anticipated by Day is being maintained for the reasons stated in the previous office action.
2. The rejection of claims 22, 24-26 and 42 under 35 U.S.C. 102(b) as being anticipated by Day is hereby withdrawn.
3. The rejection of claims 27 and 38 under 35 U.S.C. 102(e) as being anticipated by Sachetto is being maintained for the reasons stated in the previous office action.
4. The rejection of claim 15 under 35 U.S.C. 103(a) as being unpatentable over Day is being maintained for the reasons stated in the previous office action.
5. The rejection of claim 39 under 35 U.S.C. 103(a) as being unpatentable over Sachetto is being maintained for the reasons stated in the previous office action.

### ***Allowable Subject Matter***

6. Claims 3, 6, 22, 24-26, 42, 43 and 45-56 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

Art Unit: 1616

7. The indicated allowability of claims 33 and 37 is withdrawn. Rejections based on the reference(s) follow.

Rejection of claims 33 and 37 will fall under the same rejection as claim 27 and 38 over Sachetto.

### ***Response to Arguments***

8. Applicant's arguments filed August 16, 2005 have been fully considered but they are not persuasive.

Applicants argue that the prior art reference of Day does not teach the treatment of inflammatory bowel disease with a polysaccharide selected from xanthan gum and hydroxypropylmethylcellulose (HPMC) together with a pharmaceutically acceptable carrier or vehicle. Claims 1 and 2 are directed towards a composition comprising a polysaccharide and a carrier or vehicle, which is described in the prior art of Day. The treatment of inflammatory bowel disease is an intended use for the composition and carries no patentable weight. With respect to the intended use in a claim for a composition, a statement of intended use is of little patentable weight unless it specifically alters one or more ingredients of said composition. In re Madder et al. 143 USPQ 248. It is the position of the examiner that Sachetto teaches the claimed invention. Claim 27 is directed towards an enema comprising about 0.4 to about 2% w/w of xanthan gum and a pharmaceutically acceptable carrier or vehicle. Sachetto teaches a composition for rectal or vaginal administration comprising water, a liquefied

Art Unit: 1616

gas, a surfactant and a water-soluble polymer. The water-soluble polymer is xanthan gum or hydroxypropylmethylcellulose and is in a concentration of up to 5%.

### ***Conclusion***

9. Claims 1, 2, 15, 27, 33 and 37-39 are rejected.

**THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the mailing date of this final action.

### ***Telephone Inquiries***

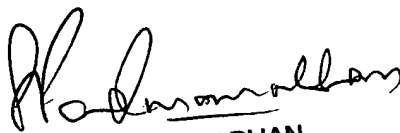
Any inquiry concerning this communication or earlier communications from the examiner should be directed to Konata M. George, whose telephone number is (571) 272-0613. The examiner can normally be reached from 8AM to 6:30PM Monday to Thursday.

Art Unit: 1616

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Kunz, can be reached at (571) 272-0887. The fax phone numbers for the organization where this application or proceeding is assigned are (571) 273-8000 for regular communications and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Konata M. George

  
SREENI PADMANABHAN  
SUPERVISORY PATENT EXAMINER